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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,286	09/19/2003	David M. Mosser	06056-0250 CT2	9066

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,286	MOSSER ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-42 are pending.

Restriction Requirement

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2-9 and 28-31, drawn to a method of inhibiting a proinflammatory immune response comprising administering effective amount of multivalent antibody or antibody multimer or IgG preparation, classified in Class 424, subclass 130.1.

II. Claims 7, 32 , 28 and 31 drawn to a method of inhibiting a proinflammatory immune response comprising administering effective amount of synthetic or recombinant peptide, classified in Class 424, subclass 184.1

III. Claims 11-17 and 33-36 , drawn to a method of treating or preventing shock associated with bacterial endotexemia comprising administering effective amount of multivalent antibody or antibody multimer or IgG preparation, classified in Class 424, subclass 130.1.

IV. Claims 16, and 37 drawn to a method of treating or preventing shock associated with bacterial endotexemia comprising administering effective amount of synthetic or recombinant peptide, classified in Class 424, subclass 184.1

V. Claims 19-27 and 38-41, drawn to a method of treating an autoimmune disorder comprising administering effective amount of multivalent antibody or antibody multimer or IgG preparation, classified in Class 424, subclass 130.1.

VI. Claims 24, and 42 drawn to a method of treating an autoimmune disorder comprising administering effective amount of synthetic or recombinant peptide, classified in Class 424, subclass 184.1

It is noted that : (i) Claim 1 is linking claim and will be examined along with claims of Group I or Group II if one of the said Group is elected; (ii) Claim 10 is linking claim and will be examined along with claims of Group III or Group IV if one of the said Group is elect; (iii) Claim 18 is linking claim and will be examined along with claims of Group V or Group VI if one of the said Group is elect.

3. Groups I- VI are different methods. These inventions are different with respect to ingredients, method steps, and etiologies and therapeutic endpoints of pathological conditions which require non-coextensive searches ; therefore, each method is patentably distinct.

Species Election

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

4. If Groups I or II is elected, applicant is required to elect a specific method of inhibiting a proinflammatory immune response, wherein a specific cross-linking reagent is homobifunctional cross-linking reagent selected from the group recited in claim 30 or heterobifunctional cross-linking reagent selected from the group recited in claim 31.

These species are distinct because the methods of inhibiting a proinflammatory immune response, wherein a specific cross-linking reagent is homobifunctional cross-linking reagent selected from the group recited in claim 30 or heterobifunctional cross-linking reagent selected from the group recited in claim 31 differ with respect to the specific cross-linking reagent; thus each specific method employing a specific cross-linking reagent represents patentably distinct subject matter.

5. If Groups III or IV is elected, applicant is required to elect a specific method of treating or preventing shock associated with bacterial endotexemia, wherein a specific cross-linking reagent is homobifunctional cross-linking reagent selected from the group recited in claim 35 or heterobifunctional cross-linking reagent selected from the group recited in claim 36.

These species are distinct because the methods of treating or preventing shock associated with bacterial endotexemia, wherein a specific cross-linking reagent is homobifunctional cross-linking reagent selected from the group recited in claim 35 or heterobifunctional cross-linking reagent selected from the group recited in claim 36 differ with respect to the specific cross-linking reagent; thus each specific method employing a specific cross-linking reagent represents patentably distinct subject matter.

6. If Groups V or VI is elected, applicant is required to elect a specific method of treating an autoimmune disorder, wherein: (i) a specific cross-linking reagent is homobifunctional cross-linking reagent selected from the group recited in claim 40 or heterobifunctional cross-linking reagent selected from the group recited in claim 41 and (ii) specific autoimmune disease is selected from the group recited in claim 25.

These species are distinct because a specific method of treating an autoimmune disorder, wherein: (i) a specific cross-linking reagent is homobifunctional cross-linking reagent selected from the group recited in claim 40 or heterobifunctional cross-linking reagent selected from the group recited in claim 41 and (ii) specific autoimmune disease is selected from the group recited in claim 25 differ with respect to the specific cross-linking reagent and in etiologies and therapeutic endpoints of pathological conditions ; thus each specific method employing a specific cross-linking reagent and specific disease represents patentably distinct subject matter.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

A telephone call was made to Daniel Monaco on 08/19/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 23, 2004

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